

Notice of Allowability

Application No.

09/554,533

Examiner

Samuel W. Liu

Applicant(s)

BEELEY ET AL.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 2/9/07.
2. ☒ The allowed claim(s) is/are 55-62, 66-71, 74 and 75.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>3-1-07</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

The amendment filed 2/9/07 which amends cancels claims 1-54, amends claims 55-62, 66-70 and 74 has been entered. Pending claims 55-75 are examined in this Office action.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the change and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Dianne Rees on March 1, 2007. Applicants agree the Examiner proposed amendment to claims 55, 63-66 and 72-73; and applicants agree to cancel claims 63-65 and 72-73 without prejudice (see below).

Amendments to the claim:

The pending 55, 63-66 and 72-73 have been amended/deleted as follows. Please replace the previous claims with the claims shown below.

Claim 55 (*Amended*): An isolated peptide compound according to SEQ ID NO:4 and having the formula:

His Xaa₂ Xaa₃ Gly Thr Phe Thr Xaa₈ Asp Xaa₁₀ Ser Lys Gln Xaa₁₄
Glu Glu Glu Ala Val Arg Leu Xaa₂₂ Xaa₂₃ Glu Xaa₂₅ Leu Lys
Xaa₂₈ Gly Gly Pro Ser Ser Gly Ala Pro Pro Pro-Z

Wherein Xaa₂ is Ser, Gly or Thr,

Xaa₃ is Asp or Glu

Xaa₈ is Ala, Ser, or Thr,

Xaa₁₀ is Leu, Ile, Val, pentylglycine or Met,

Xaa₁₄ is Ala, Leu, Ile, pentylglycine, Val or ~~Met~~,

Xaa₂₂ is Phe, Tyr or naphthylalanine,

Xaa₂₃ is Ile, Val, Leu, pentylglycine, tert-butylglycine or Met,

Xaa₂₅ is Ala, Trp, Phe, Tyr or naphthylalanine,

Xaa₂₈ is Ala or Asn, and

Z is -OH or NH₂, wherein said peptide compound is an exendin agonist; or a pharmaceutically acceptable salt thereof.

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Delete claims 63-65.

Claim 66 (*Amended*): An isolated peptide compound according to SEQ ID NO:4 and having the formula:

His Xaa₂ Xaa₃ Gly Thr Phe Thr Ser Asp Leu Ser Lys Gln Met Glu
Glu Glu Ala Val Arg Leu Phe Ile Glu Trp Leu Lys Asn Gly Gly
Pro Ser Ser Gly Ala Pro Pro Pro-Z

Wherein Xaa₂ is ~~Gly, Ser,~~ Ala or Thr, Xaa₃ is Glu or Asp; and Z is -OH or NH₂, wherein said peptide compound is an exendin agonist; or a pharmaceutically acceptable salt thereof.

Delete claims 72-73.

Amendments to the specification:

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is added as follows.

The present invention relates to novel exendin agonist compounds useful in treatment of Type I and II diabetes, and useful in lowering plasma glucose levels, reducing body weight, and delaying and/or slowing gastric emptying.

The following is an **Examiner's Statement of Reasons for Allowance**: In light of the applicants' amendment filed 2/9/07, the objection to claims 55-62, 66-71 and 74-75, and the rejection to claims 55-62, 66-71 and 74-75 under 35 USC 101 (non-statutory) are withdrawn in light of the applicants' amendment filed 2/9/07. The rejections under 35 USC 102(e) to claims 55, 57-60, 62, 66, 69-70 and 74, and the rejection under 35 USC 103 to claims 55-62, 66-70 and 74 are withdrawn hereon in light of the following reason. The applicants argue that the provisional applications 60055404 filed 8/8/1997 and 60034905 filed 1/17/1997 of which US Pat. No. 6956026 (Beeley et al.) claims for benefit do not disclose the instant sequence set forth in claims 55 and 66; i.e., 102(e) date of Beeley et al. patent is neither 8/8/1997 nor 1/17/1997, and thus, 6956026 is not qualified for the 102(e) prior art against the current invention. The applicants' argument is persuasive. Thus, the 102(e) rejection to claims 55, 57-60, 62, 66, 69-70 and 74 falls. For the same reason, the 103(a) rejection based on 6956026 falls. The 102 and 103 rejections are withdrawn. Therefore, claims 55-62, 66-71 and 74-75 are free from the prior art.

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Conclusion: claims 55-62, 66-71 and 74-75 are allowed.


The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Any comments considered necessary by applicants must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is (571) 272-0949. The Examiner can normally be reached daily except alternate Fridays from 8:30 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Kathleen Kerr Bragdon, can be reached at (571) 272-0931. The official fax number for Technology Center 1600 is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

swL

Samuel W. Liu, Ph.D.
Art Unit 1656, Examiner
March 2, 2007


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER

Abstract

The present invention relates to novel exendin agonist compounds useful in treatment of Type I and II diabetes, and useful in lowering plasma glucose levels, reducing body weight, and delaying and/or slowing gastric emptying: